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10/516,307	12/10/2004	Hiroto Kikuchi	259431US0PCT	3909
22850	7590	05/28/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			KOSAR, AARON J	
			ART UNIT	PAPER NUMBER
			1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/516,307	Applicant(s) KIKUCHI ET AL.	
	Examiner AARON J. KOSAR	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,13-26,29 and 43-53 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-6,13-26 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/26/07; 11/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and argument filed January 11, 2008 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 30-33 and introducing new claims 43-53. Claims 1,4-6,13-26,29 and 43-53 are pending. Claims 1,4-6,13-26, and 29 remain withdrawn. **Claims 43-53** are pending and have been examined on the merits.

Claim Objections

Claims 43 and 50 are objected to because of the following informalities:

In claim 43, the phrases "purity of at least.. w/w % based on dry weight", "purity of at least..w/w%", "purity of less than 70%", and "purity of at 70 w/w% or more based on dry weight.." are objected to because the terms are internally inconsistent in the usage of the unit of measure; however, this objection may be overcome, for example, by reciting: "purity based on dry weight of at least 70%(w/w)", "a purity based on dry weight of less than 70%(w/w) and of at least 60%(w/w)", and "purity based on dry weight of 70%(w/w) or more".

Also in claim 43, please note, the unit 15 to 200 "microns" is understood to mean, but often recited presently, as the equivalent expressions 15 to 200 "µm" or "micrometers". Particle sizing also provides implicit support for the dimension of "diameter" for further describing the measured dimension (e.g versus circumference).

In claim 50, the term "with fructosyltransferase" in the absence of substrate identity (e.g. EC 4.2.2.18, inulin fructotransferase, *inulin D-fructosyl-D-fructosyltransferase*, etc.) is properly generically recited by the phrase "with a fructosyltransferase".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the unit of measure of brix (Bx, or degree brix (°Bx) as instantly recited as “R-Bx” is unclear. The unit is unclear, because it is unclear what feature/measurement the “R” in R-Bx represents. As such the abbreviated unit may have multiple broad and reasonable meanings/interpretations and thus one would thus not be able to determine the metes and bounds of the claims, thereby rendering the claims indefinite.

In claim 50 and 51, is unclear because the term “the DP of fructose” requires, but lacks an object in which “the..fructose” is contained. Thus one would not be apprised as to the metes and bounds of the compositions useful in and embraced by the claimed method; however, this ground may be overcome, for example, by reciting “the degree of polymerization of fructose in said inulin is 10 or more”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 45, and 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over TANAKA (**AP**:PTO-1449, 12/10/2004: English Abstract; **N**:PTO-892, English Translation) *or* UCHIYAMA (US 5,057,418) *or* TOMITA (PTO-892, **N**, 3/20/2007(Derwent – English abstract of JP 03-259090), *and* in view of ARMAREGO (Armarego, W.L.F. and Perrin, D.D. “Common Physical Techniques Used in Purification”, Purification of Laboratory Chemicals, *4th Ed.*, 1996, chapter 1, pages 1-3 and 12-27.)

The claims are generally drawn to a method of purifying (i) a DFA III composition to provide (ii) a purified DFI III comprising contacting (i) with activated carbon, phase separation, and recovery of DFA III. The claims are also in general further drawn to percentages, relative quantities, and dimensions of the components.

TANAKA teaches the DFA product in solution (500 ml extract); less than 70% pure (0.5g DFA recoverable per 500 ml extract); the use of yeast, including fermenting with the aerobe *A. ureafaciens*; defecation (filtering boiled/sliced burdock); adsorption onto active carbon; filtering to separate the solid carbon adsorbate from the liquid filtrate; and chromatographing with HIGH-FLOW SUPERCELL (eluted with 5% ethanol) in the purification of the difructose dianhydride product (English abstract; English translation: page 4, ¶1-2; page 5 ¶1 and 3).

UCHIYAMA (US 5,057,418) teaches a process for preparing DFA III comprising obtaining DFA via a centrifuged *Arthobacter ilicus* cell-filtrate; adjusting the filtrate concentration (from 150mL to 10mL) under reduced pressure; passing the filtrate through and further purifying the DFA III-containing fraction by an activated carbon/CELITE column, and finally concentrating to dryness the eluted peaks to yield purified DFA III. Uchiyama also

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teaches that the inulin-lytic enzyme may be provided as the enzyme *per se* (an extract) or in the form of the obligate aerobic microorganism producing the enzyme (e.g. column 5, lines 4-7).

TOMITA teaches a method for purifying DFA III (Derwent- English abstract). Tomita teaches purification using centrifugation to defecate the suspended particles, and filtering by passage through activated carbon and silicates (i.e. CELITE) (Derwent- English abstract, lines 7-9). Tomita also teaches a purity of DFA III of less than 70% in that Tomita teaches a composition comprising 95% components other than inulin. Thus even 100% conversion of inulin to DFA III by the inulinase would produce a composition comprising no more than 5% DFA III. Tomita also teaches action of a fructosyltransferase upon a fructose/fructose-containing polymer by teaching the reaction of inulinase upon inulin to produce DFA III (Derwent- English abstract, line 1).

ARMAREGO teaches that “purity is a matter of degree” and that absolute purity is an unattainable ideal (page 1, ¶1). Armarego teaches that carbon (charcoal/decolorizing carbon) is useful in the removal extraneous/contaminant material for solutions by the addition of a small amount of carbon to a solution, then filtered, and that a “greater degree of purity is also to be expected if the [crystallization] process is repeated several times” (page 12, “Recrystallization: Techniques”, ¶2). Armarego further teaches that purification by filtration may be supplemented with filter aids, including the diatomaceous earth/silicates “CELITE, FLORISIL, or HYFLO-SUPERCEL” or substituted with various porosity filters (filter paper, glass fibre, sintered glass, NYLON, TEFLON, polyvinyl chloride filters, etc.) or centrifuged depending on the solvent and the nature of compounds in solution/suspension (e.g. particle size, (in)solubility)(page 13). Still further, Armarego teaches that purification of complex organic mixtures includes adsorption

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chromatography, wherein the adsorbents include “charcoal (usually mixed with kieselgurh or other form of diatomaceous earth, for example, the filter aid CELITE)” (e.g. “Graded Adsorbents and Solvents”, page 18).

TANAKA differs from the instant claims in that Tanaka appears to be silent with respect to the percentage purity and brix of the starting material and product; the quantity and quality (particle size/surface area/mesh) of carbon adsorbant used; and the sequence of contacting of the solid, liquid, and carbon.

UCHIYAMA differs from the instant claim in that Uchiyama appears to be silent with respect to the claimed percentages, amounts, and dimensions of the carbon and DFA compositions.

TOMITA differs from the instant claims in that Tomita appears to be silent with respect to the claimed purity of DFA, percentage of carbon,

It would have been obvious to use any active carbon source or any DFA III and to purify the composition to the desired purity, because ARMAREGO teaches that purity is a matter of degree and that a variety of techniques are well-established and routinely optimized for the purpose of purification, including filtration/adsorption with silicates (e.g. diatomaceous/Fuller’s earth), silica, activated carbon, etc. One would have been motivated to purify the compositions with active carbon, because TANAKA/UCHIYAMA teach in general that DFA may be purified using active carbon and HIGH-FLOW SUPERCELL/CELITE. The quality (purity, brix) of the DFA of Tanaka appears to be an obvious variant of that instantly claimed in that the compositions appear to have the same chemical core, obtained from the same composition

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(and/or commercially available materials), and would thus be expected to have similar chromatographic selectivity properties, especially as said purification relates not to the DFA but to the adsorption of the impurities therewith. Additionally, the type and amount of active carbon used also appears to be an obvious variant of the instantly claimed activated carbon in that both materials comprise active carbon and are useful for the same purpose intrinsic to activated carbon (purification, decolorizing, deodorizing, etc.). Thus the contacting of each of the starting material DFA and the carbon of any size, purity, or quantity would still be expected to interact in the manner claimed (increasing the purity of the composition), especially in the absence of criticality or objective evidence to the contrary. One would have had a reasonable expectation of success in making a purified DFA III composition, because the success depends upon contacting a DFA composition of known core structure, with activated carbon of known activity, in a known method (contacting/adsorbing), to yield a predictable result (increased purity/ removal of adsorbed impurities) and well within the purview of the skilled artisan.

Tanaka is relied upon for the reasons discussed above. If not expressly taught by Tanaka, based upon the overall beneficial teaching provided by this reference with respect culturing an aerobic bacteria, extent of purification of reagents/products, and proportions of ingredients in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable concentration ranges (e.g. aerobe culturing oxygenation/aeration; quantities, qualities, and proportions of composition components in which to perform such a purification), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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Furthermore, selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *In re Gibson*, 5 USPQ 230 - CCPA 1930). MPEP § 2144.04. Also, Selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330 - CCPA 1946) MPEP § 2144.04.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, claims 50-52 have been included in this rejection since the treating of inulin does not require an isolated, purified, or other manipulation which would distinguish an inulin conversion by an organism containing the enzyme from an (inulin) fructosyltransferase enzyme *per se*.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

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the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ajk/

Aaron Kosar
Examiner, Art Unit 1651

/Sandra Saucier/

Primary Examiner, Art Unit 1651